

PATENT

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Jane A. Walker

January 3, 2006

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Peyman

Serial No.:

10/631,143

Filed:

July 31, 2003

Group Art Unit:

1615

Confirmation No.:

2223

Examiner:

2223 Sheikh

Title:

TREATMENT OF OCULAR DISEASE

Attorney Ref.:

PMAN-23

Cincinnati, Ohio 45202

January 3, 2006

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of candor and good faith imposed by 37 C.F.R. §1.56 and means of complying therewith according to 37 C.F.R. §§1.97 and 1.98, the references listed on the attached form PTO-1449 are called to the attention of the United States Patent and Trademark Office in connection with the above-identified patent application.

Applicant has the following co-pending applications disclosing use of one or more macrolides: 10/289,772, 10/667,161, and 10/752,124. The references

submitted in this IDS are or were submitted or cited in applicant's co-pending applications, and are included in the pending application to ensure compliance with applicant's duty of disclosure under 37 C.F.R. §§1.97.

The Examiner is urged to consider the cited references listed on the attached form PTO-1449, and to make an independent decision with respect to materiality.

Applicant does not believe any fee is due with this submission. However, the Examiner is authorized to charge any fee or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

Beverly A. Lyman, Ph.D.

Reg. No. 41,961

2700 Carew Tower 441 Vine Street Cincinnati, OH 45202 513 241-2324 513 421-7269 (facsimile)

SERIAL NO. SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. PATENT AND TRADEMARK OFFICE **PMAN/23** 10/631,143 (MODIFIED) INFORMATION DISCLOSURE **APPLICANT** STATEMENT BY APPLICANT Gholam Peyman FILING DATE **GROUP** (Use several sheets if necessary) (37 CFR 1.98(b)) July 31, 2003 1615 FILING DATE **EXAMINER** ISSUE IF APPROPRIATE PATENT NUMBER DATE **PATENTEE CLASS SUBCLASS** INITIAL 7 9 0 3 8 03/14/78 Choi et al. 260 03/05/76 AA O 0 9 3 7 0 9 06/06/78 Choi et al 424 19 01/28/75 A.B 4 12/26/78 Choi et al 424 22 03/02/78 A.C 3 6 8 1 A.D 3 8 3 4 02/06/79 Choi et al 252 1 08/24/77 0 12/25/79 Choi et al 528 153 03/03/78 8 6 4 6 A.E 4 1 0 4 6 12/08/81 Heller et al 424 78 05/15/80 A.F 3 08/07/90 528 320 06/14/89 A.G 4 9 4 6 9 3 1 Helier et al 03/15/94 514 12/20/89 A.H 5 2 9 4 6 0 4 Nussenblatt et al. 11 5 4 9 5 2 05/1995 Kaswan A.I 1 1 5 4 5 7 8 2 10/10/95 Wiederrecht et al. 530 402 02/15/94 A.J 1 A.K 5 7 7 0 6 0 7 06/23/98 Honbo et al. 514 302 07/18/94 FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS TRANSLATION DOCUMENT **PUBLICATION** COUNTRY OR NUMBER DATE PATENT OFFICE **CLASS SUBCLASS** (YES/NO) A.L JP 07010752 01/13/95 JΡ A61K 31/365 N/A Abstract JΡ 9/08 N/A JP 09315954 A61K 12/09/97 A.M Abstract WO 99/22722 05/14/99 PCT A61K 31/00 N/A A.N N/A Unknow A.O AU 17386/88 Unknown ΑU Unknown Unknow Unknown N/A A.P AU 20350/92 Unknown ΑU 01/30/02 A61K 9/06 Abstract only A.Q CN 1333018 CN OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) Algvere et al., Long-term outcome of RPE allografts in non-immunosuppressed patients with AMD, European J of A.R Ophthalmology (1999) 9(3):217-230 A.S Anderson et al., A Role for Local Inflammation in the Formation of Drusen in the Aging Eye, American Journal of Ophthalmology, Vol. 134, No. 3, September 2002, pp. 411-431 A.T Aramant et al., Retinal transplanatation, Science & Medicines (2000), 7:20-29 **EXAMINER** DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered.

Include a copy of this form with next communication to applicant.

Sheet _2(B)_ of _ 16

U.S. DEPARTMENT OF COMMERCE SUBSTITUTE FORM PTO-1449 ATTY, DOCKET NO. SERIAL NO. PATENT AND TRADEMARK OFFICE PMAN/23 10/631,143 (MODIFIED) INFORMATION DISCLOSURE **APPLICANT** Gholam Peyman STATEMENT BY APPLICANT **FILING DATE GROUP** (Use several sheets if necessary) July 31, 2003 1615 (37 CFR 1.98(b)) U.S. PATENT DOCUMENTS **EXAMINER** ISSUE FILING DATE **SUBCLASS** IF APPROPRIATE PATENT NUMBER **PATENTEE CLASS** INITIAL DATE B.A 5 7 3 0 1 9 06/30/98 Ashton et al 424 423 09/27/95 B.B 5 9 5 2 3 7 09/14/99 Baker et al. 514 443 10/08/97 1 B.C 5 6 8 5 4 10/19/99 424 425 12/05/97 9 3 Heller et al. B.D 6 0 0 4 5 6 5 12/21/99 Chiba et al. 424 278.1 09/23/97 9 01/30/01 604 265 01/28/99 6 7 8 7 B.E 1 1 Zhong B.F 6 2 3 9 3 05/29/01 514 29 06/02/99 Dawson et al. 05/29/01 428 423 02/07/97 B.G 6 2 3 8 7 9 9 Opolski 07/10/01 514 912 07/10/01 B.H 6 2 5 8 8 5 6 Chamberlain et al B.I 6 3 0 6 4 2 2 10/23/01 Batich et al 424 423 08/03/98 B.J 6 3 5 0 4 4 2 02/26/02 Garst 424 78.04 05/30/01 B.K 6 4 1 3 5 3 6 07/02/02 Gibson et al 424 423 08/27/99 FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS DOCUMENT **PUBLICATION** COUNTRY OR TRANSLATION PATENT OFFICE **SUBCLASS** (YES/NO) NUMBER CLASS DATE B.L CN 1340358 03/20/03 CN A61K 38/13 Abstract only B.M CN 1456350 11/19/2003 CN A61K 9/00 Abstract only B.N DE 19810655 09/16/99 DE A61K 38/13 Abstract only B.O EP 1142566 10/10/01 ΕP A61K 9/08 Abstract only 08/18/98 JP 38/22 Yes B.P JP 10218787 A61K JP 1997030966 JΡ 31/365 Yes B.Q 02/04/97 A61K OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) B.R Aron-Rosa, Pulsed Nd:YAG lasers in ophthalmology, Nd:YAG Laser Applications pp. 34-48 B.S Carmo et al., Effect of cyclosporin A on the blood-retinal barrier permeability in streptozotrocin-induced diabetes, Mediators of Inflammation (2000), 9(5):243-248 B.T Chiou, Topical Treatment of Ocular Hypertension, Glaucoma, Ischemic Retinopathy and Age-Related Macular Degeneration with Ophthalmic Formulation of Dopamine Antagonists, U.S. Patent Publication No. US 2003/0069232, published 04/10/03 **EXAMINER** DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Sheet 3 (C) of 16

ATTY. DOCKET NO. SERIAL NO. U.S. DEPARTMENT OF COMMERCE SUBSTITUTE FORM PTO-1449 10/631,143 PATENT AND TRADEMARK OFFICE PMAN/23 (MODIFIED) **APPLICANT** INFORMATION DISCLOSURE STATEMENT BY APPLICANT Gholam Peyman **GROUP FILING DATE** (Use several sheets if necessary) 1615 July 31, 2003 (37 CFR 1.98(b)) **U.S. PATENT DOCUMENTS** FILING DATE ISSUE **EXAMINER** IF APPROPRIATE PATENT NUMBER **PATENTEE CLASS SUBCLASS** INITIAL DATE C.A 6 4 3 6 9 0 6 08/20/02 Or et al 514 29 04/02/01 C.B 6 4 0 9 4 2 08/27/02 Or et al 514 30 12/22/00 6 2 10/2002 Castilleios C.C 6 0 7 4 C.D 6 6 2 0 2 6 10/08/02 Or et al 514 30 02/16/01 4 8 2 7 9 9 11/2002 Tuse et al C.E 6 4 13/00 01/31/01 C.F 6 5 3 4 6 9 3 03/18/03 Fischell et al. A61F 425 08/04/00 07/22/03 Nelson et al 424 6 5 9 6 2 9 6 C.G 05/11/01 09/02/03 424 462 6 3 3 5 5 Ng et al C.H 6 09/12/00 09/09/03 514 395 C.I 6 6 7 3 4 5 Gregory et al 525 462 11/14/02 7 C.J 6 6 6 3 7 1 12/23/03 Ng et al C.K 6 6 7 0 3 9 8 12/2003 Edwards et a FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS TRANSLATION COUNTRY OR **PUBLICATION** DOCUMENT SUBCLASS NUMBER DATE PATENT OFFICE **CLASS** (YES/NO) JΡ 38/22 Yes C.L JP 2001064198 03/13/01 A61K 48/00 N/A A61K C.M WO 02/24234 03/28/02 PCT Abstract only A61K 38/13 WO 03/051385 06/26/03 PCT C.N 31/00 N/A A61K C.O **PCT** WO 03/017990 03/06/03 A61K 38/13 Abstract only PCT C.P WO 2004/096261 11/11/24 05/27/04 PCT A61K 38/00 N/A WO 2004/043480 C.Q OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) Cicciarell et al., Pharmacokinetics of subconjunctivally administered cylcosporine A. Local delivery prior to chemotherapy for C.R retinoblastoma, IOVS (3/15/2001), 42(4):S332 Costantini, LC, et al., Immunophilin Ligands and GDNF Enhance Neurite Branching or Etongation from Developing C.S Dopamine Neurons in Culture, Experimental Neurology 164,60-70 (2000) Das et al., The transplantation of human fetal neuroretinal cells in advanced retinitis pigmentosa patients: Results of a long-C.T term safety study, Experimental Neurology (1999), 157:58-68 DATE CONSIDERED **EXAMINER** EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance and not considered.

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Sheet _ 15 (O) _ of _ 16 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. **SUBSTITUTE FORM PTO-1449** PATENT AND TRADEMARK OFFICE PMAN/23 10/631,143 (MODIFIED) INFORMATION DISCLOSURE **APPLICANT** Gholam Peyman STATEMENT BY APPLICANT **GROUP FILING DATE** (Use several sheets if necessary) (37 CFR 1.98(b)) July 31, 2003 1615 U.S. PATENT DOCUMENTS FILING DATE **EXAMINER ISSUE** IF APPROPRIATE **CLASS SUBCLASS** PATENT NUMBER DATE **PATENTEE** INITIAL O.A O.B O.C O.D O.E O.F O.G O.H 0.1 O.J O.K FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS **TRANSLATION** DOCUMENT **PUBLICATION** COUNTRY OR PATENT OFFICE **CLASS SUBCLASS** (YES/NO) NUMBER DATE O.L O.M O.N 0.0 O.P O.Q OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication) Shen et al., Combined effect of cyclosporine and sirolimus on improving the longevity of recombinant adenovirus-mediated O.R transgene expression in the retina, Archives of Ophthalmology (7/2001), 119(7): 1033-1043

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The stamp of the Patent Office hereon, may be taken as acknowledging the receipt, on the date stamped, of the following items in the captioned case:

Inventor(s): Serial No.:

Peyman 10/631,143 July 31, 2003 TREATMENT OF OCULAR DISEASE

Filing Date: Title:

2223

Supplemental Information Disclosure Statement; copies of 41 references; Certificate of Mailing; Return postcard Conf.No.: Enclosures:

Beverly A. Lyman, Esquire (126) WOOD, HERRON & EVANS, L.L.P.

November 22, 2005